

DEC 15 2000

K 003656

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510(K) SUMMARY FOR THE PRONOSCO X-POSURE SYSTEM™

VERSION 2 MAMMO

Submitter's Name, Address, Telephone Number, And Contact Person

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Date Prepared

November 25, 2000

Name of the Device

The Pronosco X-posure System™ Version 2 MAMMO

Common or Usual Name

Bone Densitometer

Classification Name

Bone Densitometer (21 C.F.R. § 892.1170)

Predicate Devices

1. Pronosco X-posure System™ Version 2 RAD (K002500)

Intended Use

The Pronosco X-posure System™ Version 2 MAMMO is intended for use to estimate bone mineral density ("BMD") in the forearm and to assess increased risk of osteoporotic fractures according to World Health Organization

("WHO") criteria. The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (*i.e.*, prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); and (2) compare the BMD estimate with a reference population comprised of young normals and age matched normals to compute T-scores and Z-scores, respectively.

Principles of Operation

To use the System, an image must first be taken of the subject's non-dominant hand and forearm using standard mammography equipment according to the company's imaging specifications. The image is then scanned into the X-posure System, and the software algorithm derives the BMD estimate based on analysis of cortical thickness in the second through fourth metacarpals.

Technical Characteristics

The Pronosco X-posure System Version 2 MAMMO and the predicate device possess similar technical characteristics. The method of deriving the BMD estimate (digital X-ray radiogrammetry) is identical to the previously cleared version of the X-Posure System. The principal difference in technological characteristics compared to the predicate is that Version 2 MAMMO derives the

BMD estimate from images captured using mammography equipment, while Version 2 RAD derives the BMD estimate from images captured using X-ray equipment.

Summary Basis for the Finding of Substantial Equivalence

The Pronosco X-posure System Version 2 MAMMO is substantially equivalent to the previously cleared Version 2 RAD of the device (K002500). The intended use and indications for use are identical. The principal difference in technological features from the predicate device is the image source (*i.e.*, mammography versus conventional X-ray). This difference in technical characteristics between the modified Pronosco X-posure System and the predicate does not raise any new questions of safety or effectiveness, because the question of whether the images are of sufficient quality to permit BMD analysis is common to both devices. *In vitro* performance testing and clinical testing have been conducted to verify that this difference does not impact safety or efficacy. Therefore, the devices are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Pronosco™ A/S
c/o Mr. Jonathan S. Kahn, Esq.
Hogan & Hartson, L.L.P.
555 13th Street, N.W.
WASHINGTON DC 20004-1109

Re: K003656
X-posure System™ Version 2 MAMMO
Dated: November 27, 2000
Received: November 27, 2000
Regulatory Class: II
21 CFR §892.1170/Procode: 90 KGI

Dear Mr. Kahn:

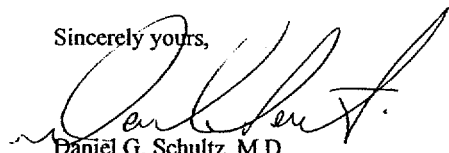
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003656

Device Name: Pronosco X-posure System™ Version 2 MAMMO

Indications For Use:

The Pronosco X-posure System™ Version 2 MAMMO is intended for use to estimate BMD and to assess increased risk of osteoporotic fractures according to World Health Organization ("WHO") criteria. The device is specifically indicated for use to: (1) assist the physician in diagnosing subjects who have already been identified to be at risk of suffering from osteoporosis, together with other known risk factors (i.e., prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of calcium and vitamin D, and smoking); (2) compare the BMD estimate with reference populations of young normals and age matched normals to compute T-scores and Z-scores, respectively.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐
(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices